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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/147,237 04/20/99 YAGI

E TOS-123-USA

HM22/0423

EXAMINER

TOWNSEND & BANTA
1225 EYE STREET NW
SUITE 500
WASHINGTON DC 20005

PRATS, F

ART UNIT	PAPER NUMBER
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1651

DATE MAILED:

04/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicant(s)

09/147,237

Applicant(s)

YAGI ET AL.

Examiner

Francisco C Prats

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19 and 20 is/are pending in the application.
- 4a) Of the above claim(s) 5-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4, 15-17, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

1. The amendment filed February 12, 2001, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.
2. Claims 19 and 20 have been added.
3. Claims 1-17, 19 and 20 are pending.

Election/Restriction

4. Claims 5-14 remain withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. As discussed immediately above, election was made without traverse in Paper No. 6, filed June 25, 1999.
5. Claims 1-4 and 15-19 are examined on the merits.

New Matter Rejection

6. Claims 19 and 20 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide prior support or antecedent basis for the language "substantially pure glutathione" in claims 19 and 20.

The claims as set forth in the amendment filed February 13, 2001, now encompass methods of treating immunosuppression and

reduced immune function by administering a composition consisting essentially of "substantially pure" glutathione. Thus, the claims now encompass processes wherein glutathione is administered in pure form, by itself with no other ingredients. However, the specification as originally filed provides only for administering glutathione in compositions containing additional ingredients.

This is a new matter rejection.

Claim Rejections - 35 USC § 112

7. Claims 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the recitation "consisting essentially of substantially pure glutathione" in claims 19 and 20 is indefinite. The term "consisting essentially of" allows for the presence of ingredients in addition to those specifically recited as being in the composition. However, the term "substantially pure" means that there are essentially no contaminating ingredients in the preparation so described. Thus, the two terms are essentially at odds. It is therefore confusing what the claim is actually reciting.

Moreover, although applicant does not discuss the facts of the *United Carbon* case, it is clear that in this instance the term "substantially pure" is itself indefinite since it is not clear what percentage of impurities is to be tolerated in the claim. This is particularly true in view of the fact that applicant has placed the term "substantially pure" adjacent to a transitional phrase allowing for any number of impurities. Moreover, applicant's application does not define the term. It is therefore respectfully submitted that a holding of indefiniteness under § 112, second paragraph, is required.

Claim Rejections - 35 USC § 102

8. Claims 1-4, 15-17, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by N'Guyen et al (U.S. Pat. 5,023,235) for the reasons of record set forth at pages 4-6 of the office action of October 13, 2000.

All of applicant's argument on this issue has been fully considered but is not persuasive of error. It is specifically noted that new claims 19 and 20 recite that the composition consists essentially of substantially pure glutathione. As discussed above, it is unclear what that limitation means precisely. It is also noted that applicant argues that the glutathione or thiol component of the N'Guyen composition

somehow couples with the EDTA or complexing agent component of the composition, thereby resulting in a reacted form of glutathione somehow chemically associated with the EDTA chelating agent, and therefore not "substantially pure" as required by the claims. Thus, construing the recitation "substantially pure" to mean "unreacted", applicant argues that the reference does not anticipate the claims.

However, it is respectfully pointed out that the reference's mention of a "complexing agent-thiol couple" does not necessarily mean that the two agents have reacted or become chemically bound in any way. The reference does not mention any specific reaction between the two species and applicant has not provided any direct evidence in support of any chemical coupling between the thiol and the complexing agent. In this regard, note specifically that the chelating agents such as EDTA used in the reference are agents which effectively remove metallic cations from solution by virtue of the ionic interaction between their negatively charged moieties and the positive charge of the dissolved ions. In either reduced or oxidized form, glutathione does not possess an ionic moiety which would allow it to become complexed to EDTA. Moreover, no specific conditions are mentioned which would allow for covalent binding between the two agents. Further still, it would appear that if any of the

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interactions proposed by applicant took place, it would defeat the purpose of the antioxidant compositions disclosed by the reference. Thus, contrary to applicant's argument, it is respectfully submitted that the reference must be considered to teach the use of glutathione in a chemically unreacted form. It is therefore respectfully submitted that the rejection remains proper and should be maintained.

Lastly, it is noted that new claims 19 and 20 recite the administered composition as one "consisting essentially of" substantially pure glutathione. It is also noted that the composition disclosed in the '235 patent contains numerous ingredients in addition to the glutathione recited in applicant's claims 19 and 20. However, as discussed in the previous office action, MPEP § 2111.03 clearly states that "[t]he transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention." (Citations omitted, emphasis in original.)

As discussed above, on the current record there is no evidence that any of the additional ingredients present in the prior art composition would affect the basic and novel properties of the prior art composition such that the prior art

composition is truly different than the claimed composition. Thus, applicant's claims must be construed as encompassing the additional ingredients in the prior art composition, despite the "consisting essentially of" language. A holding of anticipation is therefore required.

Lastly, note again that MPEP 2111.03 further provides that "[w]hen an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention."

(Citations omitted.) On the current record applicant has provided no direct evidence as required by MPEP 2111.03. It is therefore respectfully submitted that the rejection must be maintained.

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Francisco C Prats
Primary Examiner
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FCP

April 20, 2001